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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,332	06/27/2001	Joseph Solus	0942.4250003	4572
26111	7590	11/26/2003	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			TUNG, JOYCE	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/891,332		SOLUS ET AL.	
	Examiner		Art Unit	
	Joyce Tung		1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-33,66 and 69-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2, 5, 6, 9-18, 20-33 and 66 is/are rejected.
- 7) ☒ Claim(s) 7,8,19 and 69-72 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Following entry the amendment filed 8/26/2003, the claims 1-2, 5-33, 66, and 69-72 are pending.

Applicant's arguments with respect to the rejection of claims 1-2, 5-6, 9-15, 21-29 and 66 and the objection to claims 7-8, 16-20, 30-33 and 69-72 have been considered but are moot in view of the new ground(s) of rejection.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-2, 5-6, 16-18, 20, 33 and 66 are rejected under 35 U.S.C. 102(e) as being anticipated by Loeb et al. (6,395,524, issued May 28, 2002).

Loeb et al. disclose the mutant thermostable polymerase which is mutated at an active site O-helix (See, the Abstract). The mutants have been identified as having high fidelity of DNA synthesis. The mutant, polymerase has one or more single base substitution at Arg660, Phe667 (See column 12, lines 45-31). The invention provides methods copying a gene in a microsatellite DNA fragment (See column 13, lines 54-64).

Loeb et al. do not explicitly disclose the DNA polymerase which is “mutated to be substantially reduced in the ability to add one or more non-templated nucleotides to the 3' terminus of a DNA molecule” as recited in the claims. However, the phrase is interpreted as that the mutated polymerase increases the fidelity of synthesized DNA in a polymerase chain

reaction by reducing to add one or more non-templated nucleotides to the 3' terminus of a DNA molecule. Thus, the teachings of Loeb et al. anticipate the limitations of the instant claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 9-15 and 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loeb et al. (6,395,524, issued May 28, 2002) as applied to claims 1-2, 5-6, 16-18, 20, 33 and 66 above, and further in view of Caetano-Anolles et al. (WO 95/33853).

The teachings of Loeb et al. do not disclose the mutated polymerase, which is without 3'-5' or 5'-3' exonuclease activity and the kit including the mutated polymerase.

Caetano-Anolles et al. disclose a method of DNA fingerprinting in which a Stoffel fragment of a DNA polymerase from *Thermos aquaticus* is applied to the reaction. The fragment

of the DNA polymerase is a highly thermostable, recombinant DNA polymerase and no associated 3'-5' or 5'-3' exonuclease activity (See pg. 25, third paragraph).

One of ordinary skill in the art at the time of the instant invention would have been motivated to modify the method of Loeb et al. by applying the DNA polymerase of Caetano-Anolles et al. to the method of identifying, analyzing or typing a polymorphic DNA fragment in a DNA sample, because the method of Caetano-Anolles generates profiles of increased fidelity characteristic of the nucleic acids analyzed (See the Abstract). The polymerase of Caetano-Anolles was applied to the method as a part of contributions to the method. It suggests that the polymerase of Caetano-Anolles has its ability to increase the fidelity of the nucleic acid analyzed. It would have been prima facie obvious to identify, analyze or typing a polymorphic DNA fragment in a DNA sample with the mutated polymerase of Caetano-Anolles et al..

Further, one of ordinary skill in the art would have also made the kit containing the polymerase of Caetano-Anolles et al. because constructing a kit including the components used for performing a method was well known routine practice in the art for convenience. It would have been prima facie obvious to construct the kit including the mutated polymerase without exonuclease activity.

5. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loeb et al. (6,395,524, issued May 28, 2002) as applied to claims 1-2, 5-6, 16-18, 20, 33 and 66 above, and further in view of Huo (5,922,535).

The teachings of Loeb et al. are set forth in section 2 above.

Leob et al. do not disclose determining the relationship between a first individual and a second individual in which the first individual is known and the second individual is unknown via polymerase chain reaction (See the Abstract and column 1, lines 52-54).

Huo discloses the method for the detection of sequence difference between nucleic acid populations (See column 3, lines 65-67). Huo indicated that in the conventional way, the normal sequence is already known as compared with the sequence associated with a disorder (See column 1, lines 13-20).

One of ordinary skill in the art at time of the invention would have been motivated to modify the method of Huo by involving a known sequence population as taught by Huo to determine the relationship between two individual populations via polymerase chain reaction. The motivation is that the method of Huo is for the detection of sequence differences between two or more nucleic acid populations. Thus, it would have prima facie obvious to carry out the method to determine the relationship between two individuals via polymerase chain reaction.

Allowable Subject Matter

6. Claims 7-8, 19 and 69-72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter:

No prior art has been found teaching or suggesting the polymerase, The mutants, which, substantially reduces or eliminates the ability of the polymerase to add non-templated 3' nucleotides to a synthesized nucleic acid molecule.

Summary

8. No claims are allowable.
9. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

J T
November 13, 2003


**ETHAN WHISENANT
PRIMARY EXAMINER**